



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

UNDATED

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for CGA-154281

FROM: Rita Briggs, Ph.D. *RB*
Dietary Risk Evaluation System Staff
HED/SACB (H7509C)

THROUGH: Reto Engler, Ph.D.
Chief, Science Analysis and Coordination Branch
Health Effects Division (H7509C) *Reto Engler*

TO: Kerry B. Leifer
Registration Support Branch
Registration Division (H7505C)

Action Requested

Provide an estimate of exposure to the inert ingredient CGA-154281 (4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxazine), which is proposed to be used in formulations of metolachlor.

Discussion

1. Toxicology Endpoint: The DRES analysis used a reference dose of 0.005 mg/kg body weight/day, based upon a NOEL of 5.0 mg/kg body weight/day from a 90 day dog oral toxicity study and a 90 day rat toxicity study, with an uncertainty factor of 1000. This value has not been peer reviewed and is being used in this analysis to provide a preliminary estimate of exposure at the request of Registration Division (K. B. Leifer memo, 1/3/90).

2. Residue Information: Residues used in the analysis were 0.01 ppm of the contaminant for all commodities for which metolachlor (40 CFR 180.368) has a registered use (F. D. Griffith to K. B. Leifer memoranda dated 8/10/87, 3/30/88, 9/28/88, 4/3/89 and 11/21/89). A summary of the residue information used in the analysis is attached as Table 1.

3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. In this analysis, CGA-154281 residues of 0.01 ppm were assumed for all commodities for which metolachlor has a registered use. The exposure estimate

PC 94508

for the overall U.S. population is 0.000187 mg/kg body weight/day, which represents 3.7 percent of the reference dose. The TMRC exposure estimates for the two most highly exposed DRES population groups (non-nursing infants and children aged 1 to 6 are 0.000888 mg/kg body weight/day (16.2% of the RfD) and 0.000475 mg/kg body weight/day (9.5% of the RfD), respectively.

4. Dietary Risk Assessment: This analysis was conducted assuming that 100 percent of all crops for which metolachlor is registered contain 0.01 ppm of CGA-154281. Even with these extreme assumptions, the analysis indicates that a health hazard resulting from the use of CGA-154281 with metolachlor is unlikely. It must be noted, however, that the toxicology data base for an inert chemical is not as complete as for an active ingredient. Even though the reference dose is based upon the equivalent of a PADI, it is extremely unlikely that additional toxicology data will be available for this chemical.

Attachments

cc: DRES, DEB (Loranger), Caswell #188DD, Chin (TOX), Van Ormer (SACB)

Table 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 9992ZZ

DATE: 01/05/90

PAGE:

1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
METOLACHLOR INERT CGA-154281 Caswell #9992ZZ CAS No. A.I. CODE: CFR No. 180.	90 DAY DOG FEEDING NOEL= 5.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:	RfD DATA PER KERRY LIEFER REQUEST DATED 1/3/90. RESIDUE DATA PER F. D. GRIFFITH MEMO DATED 11/21/89.	UF -->1000 OPP RfD= 0.005000 EPA RfD= 0.000000	SPECIAL REQUEST. ALL PUBLISHED METOLACHLOR USES ASSUME 0.01 PPM OF THE INERT	

FOOD CODE	FOOD NAME	PETITION NUMBER	NEW	TOLERANCE (PPM) PENDING	PUBLISHED
03001AA	ALMONDS	3F2958			0.010000
03002AA	BRAZIL NUTS	3F2958			0.010000
03003AA	CASHEWS	3F2958			0.010000
03004AA	CHESTNUTS	3F2958			0.010000
03005AA	FILBERTS, HAZELNUTS	3F2958			0.010000
03006AA	HICKORY NUTS	3F2958			0.010000
03007AA	MACADAMIA NUTS (BUSH NUTS)	3F2958			0.010000
03008AA	PECANS	3F2958			0.010000
03009AA	WALNUTS	3F2958			0.010000
03010AA	BUTTER NUTS	3F2958			0.010000
03013AA	BEECHNUTS	3F2958			0.010000
05001AA	APRICOTS-FRESH	3F2957			0.010000
05001DA	APRICOTS-DRIED	3F2957			0.010000
05002AA	CHERRIES-FRESH	3F2957			0.010000
05002DA	CHERRIES-DRIED	3F2957			0.010000
05002JA	CHERRIES-JUICE	3F2957			0.010000
05003AA	NECTARINES	3F2957			0.010000
05004AA	PEACHES-FRESH	3F2957			0.010000
05004DA	PEACHES-DRIED	3F2957			0.010000
05005AA	PLUMS(DAMSONS)-FRESH	3F2957			0.010000
05005DA	PLUMS-PRUNES(DRIED)	3F2957			0.010000
05005JA	PLUMS, PRUNE-JUICE	3F2957			0.010000
08015AA	DILL	1F2495			0.010000
11003AB	CHILI PEPPERS	5E3236			0.010000
13007AA	CABBAGE-GREEN AND RED	8E3637			0.010000
13010AA	CABBAGE-CHINESE/CELERY, INC. BOK CHOY	8E3637			0.010000
14013AA	POTATOES(WHITE)-WHOLE	9F2203			0.010000
14013AB	POTATOES(WHITE)-UNSPECIFIED	9F2203			0.010000
14013AC	POTATOES(WHITE)-PEELED	9F2203			0.010000
14013DA	POTATOES(WHITE)-DRY	9F2203			0.010000
14013HA	POTATOES(WHITE)-PEEL ONLY	9F2203			0.010000
15001AA	BEANS-DRY-GREAT NORTHERN	1F2495			0.010000
15001AB	BEANS-DRY-KIDNEY	1F2495			0.010000
15001AC	BEANS-DRY-LIMA	1F2495			0.010000
15001AD	BEANS-DRY-NAVY (PEA)	1F2495			0.010000
15001AE	BEANS-DRY-OTHER	1F2495			0.010000
15001AF	BEANS-DRY-PINTO	1F2495			0.010000
15002AA	BEANS-SUCCULENT-LIMA	1F2495			0.010000
15003AA	BEANS-SUCCULENT-GREEN	1F2495			0.010000
15003AB	BEANS-SUCCULENT-OTHER	1F2495			0.010000

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 01/05/90

PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
METOLACHLOR INERT CGA-154281 Caswell #999222 CAS No. A.I. CODE: CFR No. 180.	90 DAY DOG FEEDING NOEL= 5.0000 mg/kg 0.00 ppm LEL= 0.0000 mg/kg 0.00 ppm ONCO:	RfD DATA PER KERRY LIEFER REQUEST DATED 1/3/90. RESIDUE DATA PER F. D. GRIFFITH MEMO DATED 11/21/89.	UF -->1000 OPP RfD= 0.005000 EPA RfD= 0.000000	SPECIAL REQUEST. ALL PUBLISHED METOLACHLOR USES ASSUME 0.01 PPM OF THE INERT	

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY)		NEW TMRC AS PERCENT OF RfD	DIFFERENCE AS PERCENT OF RfD	EFFECT OF ANTICIPATED RESIDUES	
	CURRENT TMRC*	NEW TMRC**			ARC	%RfD
U.S. POPULATION - 48 STATES	0.000187	0.000187	3.739120	0.000000		
U.S. POPULATION - SPRING SEASON	0.000177	0.000177	3.546500	0.000000		
U.S. POPULATION - SUMMER SEASON	0.000187	0.000187	3.739040	0.000000		
U.S. POPULATION - FALL SEASON	0.000192	0.000192	3.844800	0.000000		
U.S. POPULATION - WINTER SEASON	0.000190	0.000190	3.804600	0.000000		
NORTHEAST REGION	0.000189	0.000189	3.771040	0.000000		
NORTH CENTRAL REGION	0.000191	0.000191	3.828640	0.000000		
SOUTHERN REGION	0.000174	0.000174	3.483020	0.000000		
WESTERN REGION	0.000199	0.000199	3.978200	0.000000		
HISPANICS	0.000230	0.000230	4.603860	0.000000		
NON-HISPANIC WHITES	0.000185	0.000185	3.692260	0.000000		
NON-HISPANIC BLACKS	0.000177	0.000177	3.542000	0.000000		
NON-HISPANIC OTHERS	0.000207	0.000207	4.143460	0.000000		
NURSING INFANTS (< 1 YEAR OLD)	0.000209	0.000209	4.172500	0.000000		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000808	0.000808	16.167680	0.000000		
FEMALES (13+ YEARS, PREGNANT)	0.000132	0.000132	2.639520	0.000000		
FEMALES 13+ YEARS, NURSING	0.000162	0.000162	3.248240	0.000000		
CHILDREN (1-6 YEARS OLD)	0.000475	0.000475	9.491980	0.000000		
CHILDREN (7-12 YEARS OLD)	0.000307	0.000307	6.144600	0.000000		
MALES (13-19 YEARS OLD)	0.000202	0.000202	4.035800	0.000000		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000157	0.000157	3.146940	0.000000		
MALES (20 YEARS AND OLDER)	0.000125	0.000125	2.500100	0.000000		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000108	0.000108	2.156520	0.000000		

*Current TMRC does not include new or pending tolerances.

**New TMRC includes new, pending, and published tolerances.